DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 7, 2016

Yidobio Inc.
Kyung Hee Yoon
Excutive Director
#3-1, 59-12, Dong-gil, Hyangnam-eup, Hwaseong-si
Gyeonggi-do 18624
KOREA

Re: K160575
Trade/Device Name: CareSens Pen Needle and Softip Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 29, 2016
Received: August 10, 2016

Dear Kyung Hee Yoon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160575

Device Name
CareSens Pen Needle and Softip Pen Needle

Indications for Use *(Describe)*

The CareSens Pen Needle and Softip Pen Needle are intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

YIDOBIO

510(k) SUMMARY – K160575

A summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

1. **Prepared by:**

Joon Ho Jung
Regulatory Affairs
i-SENS, Inc.
Tel. +82-02-910-0453
Fax. +82-02-942-2514

2. **Prepared for:**

Owner/Operator
YidoBio Inc.
59-12, Dongo4-gil, Hyangnam-eup
Hwaseong-si, Gyeonggi-do

3. **Contact person:**

Kyung Hee Yoon
Executive Director
YidoBio Inc.
59-12, Dongo4-gil, Hyangnam-eup
Hwaseong-si, Hyangnam-eup

4. **Date Prepared:** February 1, 2016

5. **Subject Device:**

Proprietary Name:	CareSens Pen Needle and Softip Pen Needle
Common Name:	Insulin Pen Needle
Regulation Name:	Needle, Hypodermic, Single Lumen
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Regulatory Class:	Class II

6. **Device Description**

YIDOBIO

CareSens Pen Needle and Softip Pen Needle are sterile, non-toxic, non-pyrogenic, single-use injection needles intended for use with injection pens. This needle is a device for subcutaneous injection of medicines such as insulin and exenatide used with pen injectors for subcutaneous injection. CareSens Pen Needle and Softip Pen Needle are the same product in exception to the brand name.

7. Predicate Device

The legally marketed device(s) to which substantial equivalence is claimed is/are:

- K063466 TopFine® Insulin Pen,
  Manufactured by Daejin Tech Medical Manufacturing Co., Ltd., Korea

Regulation Name:	Needle, Hypodermic, Single Lumen
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Regulatory Class:	Class II

7.1 Reference device

- K131358 BD 31G and 32G Extra Thin Wall (XTM) Pen Needles with PentaPoint, manufactured by Becton, Dickinson and Company, New Jersey.

Regulation Name:	Needle, Hypodermic, Single Lumen
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Regulatory Class:	Class II

8. Reason for 510(K) Submission

This 510(k) is submitted to demonstrate substantial equivalence to the predicate device. CareSens Pen Needle and Softip Pen Needle. CareSens Pen Needle and Softip Pen Needle are the same product in exception to the brand name.

The specifications of the product are as follows:

No.	Gauge (Outer diameter of Needle)	Length of needle	Weight

YIDOBIO

		(mm) ℓ	(g)
1	30G (0.298mm ~ 0.320mm)	8mm(5/16")	1.22
2	31G (0.254mm ~ 0.267mm)	5mm(3/16")	
3		6mm(1/4")	
4		8mm(5/16")	
5	32G (0.229mm ~ 0.241mm)	4mm(5/32")	
6		5mm(3/16")	
7		6mm(1/4")	
8	33G (0.204mm ~ 0.215mm)	4mm(5/32")	

9. Indication For Use

The CareSens Pen Needle and Softip Pen Needle are intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.

10. Technological Characteristics

Comparison with Predicate Device (K063466 TopFine Insulin Pen Needle)

The subject device, CareSens Pen Needle and Softip Pen Needle are similar in its intended use, principle of operation, design construction, sizes, material, and sterilization method. The subject device and predicate device both completed biocompatibility and sterility testing with similar results.

The subject device and the predicate device are classified under 21 CFR 880.5570, which states: "A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin." The proposed device and the predicate device use statements similar in that they both are used with pen injector devices for subcutaneous injection of fluids, including insulin. The subject device is also used to inject exenatide.

Similarities between the Subject Devices and the Predicate Device		
Item	**Topfine Insulin Pen Needle** ***(k063466, Predicate device)***	**CareSens Pen Needle and Softip Pen Needle** ***(subject device)***
Intended use	Intended for subcutaneous injection of insulin in the treatment of diabetes.	Intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.
Operation Principle	To be used with pen injectors/Single use	Same

Design/Construction	• Needle assembly (cannula, needle hub, protector cap)	Same
Material	• Outer cap – Polypropylene • Inner Cap – Polyethylene • Needle – 304 Stainless • Needle Silicone – Polydimethylsiloxane • Needle Hub – Polypropylene	Same
Gauges/ length of needle	30G 8mm, 31G 5mm, 31G 6mm, 31G 8mm, 32G 4mm, 32G 5mm, 32G 6mm, 33G 4mm	Same
Sterilization **Biocompatibility**	EO Gas sterilization In accordance to ISO 10993	Same

Comparison with the Reference Device (K131358 BD 31G and 32G Extra Thin Wall (XTM) Pen Needles with PentaPoint)

The reference device is used in comparison for performance bench testing in accordance to ISO 11608-2. The reference device is also indicated for use of the injection of both insulin and exenatide.

Similarities between the Subject Devices and the Reference Device		
Item	**CareSens Pen Needle and Softip Pen Needle** ***(subject device)***	**BD 31G and 32G Extra Thin Wall (XTM) Pen Needles with PentaPoint** ***(K131358, Reference Device)***
Intended use	CareSens Pen Needle and Softip Pen Needle are Intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.	BD Pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.
Operation Principle	To be used with pen injectors/Single use	Same
Design/Construction	• Needle assembly (cannula, needle hub, protector cap)	Same

Material	• Outer cap – Polypropylene • Inner Cap – Polyethylene • Needle – 304 Stainless • Needle Silicone – Polydimethylsiloxane • Needle Hub – Polypropylene	• Outer cap – Unknown plastic • Inner Cap – Unknown plastic • Needle – Stainless steel • Needle Silicone – Unknown • Needle Hub – Unknown plastic
Sterilization	EO Gas sterilization	Gamma irradiation
Performance Bench	ISO 11608-2	ISO 11608-2

Bench tests relating to the performance of CareSens Pen Needle and Softip Pen Needle were conducted. Testing to voluntary standards ISO 11608-2 provides additional evidence that the performance of CareSens Pen Needle and Softip Pen Needle demonstrated equivalent performance to the Reference Device.

11. Summary of performance tests

Dimension testing	ISO11608-2:2012 (4.2 Dimensions / 4.2.1 General / 4.2.2 Dimensions for needles), meets requirements
Flow rate testing	ISO11608-2:2012 (4.3 Determination of flow rate through the needle), meets requirements
Bond between hub and needle tube testing	ISO11608-2:2012 (4.4 Bond between hub and needle tube), meets requirements
Needle point freedom from defects lubrication test	ISO11608-2:2012 (4.5 Needle point / 4.6 Freedom from defects / 4.7 Lubrication), meets requirements
Dislocation of measuring point at patient end	ISO11608-2:2012 (4.8 Dislocation of measuring point at patient end), meets requirements
Compatibility of needles and injector system test / Ease of assembly and disassembly.	ISO11608-2:2012 (4.9 Determination of functional compatibility with needle-based injection systems / 4.10 Ease of assembly and disassembly), meets requirements

Biocompatibility

Biocompatibility testing of the subject device, Softip Pen Needle and CareSens Pen Needle, were conducted so ensure no physical harm on the human skin. Results of the testing demonstrate that the device is biocompatible. Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained. Results of the testing demonstrate that the device is biocompatible.

No.	Test Items	Test Method	Result
1	Cytotoxicity test	ISO 10993-5, Tests for in vitro Cytotocity, Test on extracts	Non-Cytotoxic

2	Intracutaneous (Intradermal) Reactivity Test	ISO 10993-10, Intracutaneous(Intradermal) reactivity test	Negligible
3	Sensitization Test(Guinea pig maximization test)	ISO 10993-10, Sensitization(Guinea pig maximization test)	Weak sensitizer
4	Acute systemic toxicity test	ISO 10993-11, Acute systemic toxicity	Non-toxic
5	Pyrogen test	ISO 10993-11, USP Rabbit Pyrogen Test	Non-pyrogenic
6	Haemolysis test	ISO 10993-4, Haemolysis testing-general considerations	Non-hemolytic

Sterilization

EO gas sterilization method is utilized for assuring sterility of the subject device, Softip Pen Needle and CareSens Pen Needle. The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135. The sterilization validation has provided a Sterility Assurance Level (SAL) of 10^{-6}.

No.	Test items	Test Method	Result
1	Packaging	The case of injection or outer package should keep clean from microorganism and should not be broken before use. Also needle should be packed one by one.	PASS
2	Sterility Test-Direct inoculation	The Korean pharmacopoeia Tenth edition (same as the FDA recognized consensus standard "USP 25<71> sterility test" are the same in test protocol.)	PASS
3	Ethylene oxide sterilization residuals	If the product is sterilized by EO gas, it should be tested in accordance with ISO 10993-7, Ethylene oxide sterilization residuals. . The Sterilant Residual Limits per ISO 10993-7 for a limited exposure (<24 hours) device is as follows: EO ≤4 mg first 24 hrs and ECH ≤9 mg first 24 hrs.	PASS

12. Conclusion:

Based on the submitted information in this premarket notification, the subject devices are substantially equivalent to the predicate device.